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**Date: 01 June 2005**

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Our Ref: 040270WOMD

**Re: Informal comments on written opinion of the International Searching Authority**  
**Patent Application No.: PCT/HU2005/000002**  
**Applicant: Richter Gedeon Vegyészeti Gyár RT.**

Dear Sirs,

After receiving and studying the Written Opinion (hereafter WO) dated on 02.05.2005 we would like to send our comments.

The following reference: Walker K., A., M. et al; J. Med. Chem., 1978, Vol. 21, No. 8, pp 840-843 is signed D1.

In WO the officer states that D1 destroys the novelty of claims 1, 2 and 11. He says D1 discloses butoconazole nitrate having a melting point of 162-163 °C, so D1 discloses this compounds in any degree of purity, and in any desired particle size.

According to our judgement the subject-matter of claims 1, 2 and 11 is not disclosed in the available prior art. The subject matter of Claims 1 and 2 is novel since neither the high purity of the claimed compound (maximum 0.1 wt % of chemical impurities) nor the high purity of this compound with special particle size have never been obtained in the prior art.

The subject-matter of Claims 1 and 2 can only be produced with a particular method which was not known before the priority date, consequently the subject-matter of Claims 1 and 2 inventions as such were not known before this date.

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## GEDEON RICHTER LTD.

### TELEFAX

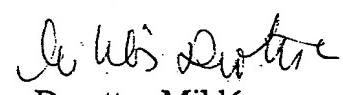
Such a high purity grade of a product can not be achieved only with recrystallization; it can be achieved if already the last intermedier of the production is obtained via a special production route, in a very high purity. From this aspect it is a wrong to assume that a skilled person would dispose of many methods to get any desired purity and particle size.

According to the above mentioned the subject-matter of Claims 1, 2 meets the requirements of novelty and inventive step (fulfils the Art. 33(2) and Art 33(3) PCT respectively) so it can be patented.

Please acknowledge the safe receipt of this fax.

Yours sincerely,

  
dr. Polgár István  
Director, Intellectual Property

  
Dorottya Miklós  
Intellectual Property Department